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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/614,473	Applicant(s) CAMPION ET AL.	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-49 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-32, 34, 35 and 39-49 is/are rejected.
- 7) ☒ Claim(s) 33 and 36-38 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-28-03</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Objections

1. Claim 30 is objected to because of the following informalities:
“hemocompatibility” is misspelled. Appropriate correction is required.
2. Claim 38 is objected to because of the following informalities: The claim does not end in a period. Appropriate correction is required.
3. Claims 43 and 45 are objected to because of the following informalities: “the second wire” lacks antecedent basis in Claim 45, and in Claim 43, “a wire” appears it should read as “a second wire”. Appropriate correction is required.
4. Claim 46 is objected to because of the following informalities: “a first wire” is stated in line 2, however Claim 42 also states “a first wire”, which leads the Examiner to believe that the dependency of the claim is incorrect or the phrase should read as “the first wire”. Appropriate correction is required.
5. Claims 47 and 38 are objected to because of the following informalities: The claims recite the use of “the wire” in line 2 of the claims, but it is unclear if “the wire” is either the “coil wire” or the “first wire”. Appropriate correction is required.
6. Claim 49 is objected to because of the following informalities: Claim 49 is a substantial duplicate of Claim 46. Appropriate correction is required.

Specification

7. The abstract of the disclosure is objected to because the abstract exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 42-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite the use of the coil wire being comprised of "a first wire" and "a second wire", however, the specification does not disclose two different wires at the distal section of the guidewire. The specification only supports a single wire being comprised of differing material properties.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 29-31, 34, 35, 39, 40 and 42-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al (5,664,580).

Erickson et al disclose a guidewire having a bimetallic coil and further disclose an elongate wire including a core having an outer surface having an area per unit length, a

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tubular layer disposed about the core having an inner surface having an area per unit length of no more than the area per unit length of the outer surface of the core, wherein a portion of the layer has a topology of a single lumen tube; wherein the elongate wire has a first property over a first portion and a second property over a second portion, wherein the first property differs from the second property, and wherein the elongate wire is formed into a coil; the first and second properties are radiopacity; at least some of the first property is provided by the layer; the layer is a material coating; the coating comprises a different material than the core; the coil is helically disposed about a guidewire distal portion; a core wire having a distal end portion and a proximal end portion and a circular cross-section decreasing in diameter at the distal end portion toward a distal end of the core wire; a coil wire having a constant diameter provided coaxially with the core wire and provided on the distal end portion of the core wire, the core wire including a first wire of different constituent materials; the coil wire includes a wire, a distal end portion of which is formed of a radiation impermeable material and a remaining portion of which is formed of a radiation permeable and elastic material; the radiation impermeable material of the first wire is selected from the group of platinum, gold and iridium; the radiation impermeable and elastic material of the second wire is either tungsten or an alloy of tungsten; and the radiation impermeable material is either platinum, gold or tungsten. See Column 5, lines 22-55.

Claim Rejections - 35 USC § 103

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12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al (5,664,580) as applied to claim 29 above, and further in view of Jalisi (6,679,853 B1).

Erickson et al, as discussed above, disclose a guidewire with a layer disposed about the core, but fail to disclose the layer is a sleeve.

Jalisi discloses a composite radiopaque guidewire and further discloses the layer is a sleeve. See Column 5, lines 20-26.

Since both Erickson et al and Jalisi disclose means for covering the coil wire, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Erickson et al to include the use of a sleeve, as per the teachings of Jalisi, since it would provide an alternative means of covering the coil wire.

14. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al (5,664,580) as applied to claim 29 above, and further in view of Rooney et al (6,306,105 B1).

Erickson et al, as discussed above, disclose a guidewire but fail to disclose the pitch of the coil at a first section is different than the pitch of the coil at a second section.

Rooney et al disclose a guidewire coil and further disclose the pitch of the coil at a first section is different than the pitch of the coil at a second section. See Figure 1.

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Since both Erickson et al and Rooney et al disclose guidewire coils, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire coil of Erickson et al to include the use of differing pitches, as per the teachings of Rooney et al, since it would provide a means of varying the stiffness at the distal end of the guidewire.

Allowable Subject Matter

15. Claims 33 and 36-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: Claim 33 contains allowable subject matter since no prior art could be found predating the priority date of the current application wherein a polymeric sleeve is placed over the elongate wire, wherein the wire is formed into a coil for a guidewire. Claim 36 contains allowable subject matter since no prior art could be found predating the priority date of the current application wherein the elongate wire further comprises a second layer disposed on a portion of the core free from the first layer. Claim 38 contains allowable subject matter since no prior art could be found predating the priority date of the current application wherein the first layer of disposed on noncontiguous portions of the core.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art of Huter et al, Ferrera and Nguyen et al all disclose various guidewire means utilizing coatings to obtain the preferred guidewire properties.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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